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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,446	01/18/2000	HUGH W. PRICE	7841-89	5954

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	18

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/402,446	Applicant(s) PRICE ET AL.15	
	Examiner Ja-Na Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-29,31-39 and 57-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-29, 31-39 and 57-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152) .
6) ☐ Other:

DETAILED ACTION

Amendment Entry

1. The amendment filed October 9, 2002 has been entered. Claims 30 and 40-56 have been deleted. New claims 57-73 have been newly added. Therefore, claims 23-29, 31-39 and 57-73 are under consideration in this Office Action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments:

a) the new matter and enablement rejections of claims 40-56 under 35 U.S.C. 112, first paragraph;

b) the rejections of claims 23-56 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

c) the rejection of claims 40, 43, 47, 49-51 and 53-54 under 35 U.S.C. 102(b) as being anticipated by Alberici et al., WO 94/16728;

d) the rejection of claims 40-51 and 53-55 under 35 U.S.C. 103(a) as being unpatentable over Friesen (CA 1,168,152) in view of de Burgh Bradley et al., (1,303,533); and

e) the rejection of claims 39 and 56 under 35 U.S.C. 103(a) as being unpatentable over Friesen (CA 1,168,152) and de Burgh Bradley et al., (1,303,533) as applied to claims 23 and 40 above, and further in view of Eibl et al., (US Patent 4,276,283).

New Grounds For Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising steps for increasing the serum half-life of an immune globulin such as: making an immune globulin preparation with the recited components i.e., non-ionic surface active agents in a formulation to prolong the half-life of the immune globulin; and administering parenterally the preparation to an animal in need thereof an immune globulin preparation, does not reasonably provide enablement for a method of increasing the serum half-life of an immune globulin comprising combining parenterally administering to an animal in need thereof an immune globulin preparation or the use of two or more non-ionic surface active agents in said preparation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims recite a method of increasing the serum half-life of an immune globulin comprising parenterally administering to an animal in need thereof an immune globulin preparation. However, the claims recite that merely administering the preparation will increase the serum half-life, since "administering" is the only active step in the claims. The specification

teaches: immune globulin preparation including non-ionic surface active agents; therapeutic dosage of the immune globulin preparation; parenteral administration of the preparation; and using the pharmacokinetics methods wherein regression were performed on log transformed corrected serum levels against time to determine the estimated half-life of the drug in subjects, see pages 19-25 of the instant specification. The specification teaches that the entire method may result in increasing the serum half-life and are necessary to achieve the claimed results, not just administering the preparation. The specification does not teach examples of said method using two or more non-ionic surface agents. Thus, simply mentioning the use of two or more agents in the claims does not provide enablement for a method that has no recited steps; neither does the recitation provided guidance on what combinations of agents can or cannot be used together and how many agents are useable in the preparation. The specification does not teach how to achieve the increased serum half-life merely by administering the preparation at all, nor does the specification teach the use of multiple surface-active agents in a preparation. Thus, the method recited in the claims does not teach the inclusion of the other necessary steps and the claims are rejected.

4. Claims 57-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have added new claims 57-73 drawn to a method for increasing serum half-life of a polyclonal immune globulin. Applicants failed to point to support in the specification,

thus it appears that the amendment lacks support. There is no teaching of a method for increasing serum half-life of polyclonal immune globulins. Moreover, the specification fails to recite method steps for this method, regarding the type of immune globulin, the purity and weight percent of the immune globulin, or the non-ionic surface-active agents. There is no teaching of the claimed method or method steps that that increases serum half-life using two or more non-ionic surface-active agents. Applicants have not pointed to support for the method by page and line number. Therefore, the claims are rejected for incorporating new matter.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 23, 26, 31-34 and 36-37 under 35 U.S.C. 102(b) as being anticipated by Alberici et al., WO 94/16728 is maintained for reasons already of record.

Applicant argues that Alberici et al., teach an antibody formulation with an antibody concentration of 0.01-1.0%, preferably 0.1% by weight. However it is the examiner's position that Alberici et al., teach a composition comprising 0.1 to 10g of monoclonal antibody. This amount falls within the claimed range. Therefore, Alberici et al., teach administering to an animal an immune globulin preparation comprising an immune globulin and at least one non-

ionic surface-active agent, polyoxyethylene sorbitan monooleate which is in a concentration sufficient to increase the serum half-life.

It should be noted that, the recitation of a method of increasing the serum half-life of an immune globulin, has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claimed method only positively recites a combination step and administration step, both of which Alberici et al., teach; therefore Alberici et al., meet the claimed limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The rejection of claims 23-34 and 36-38 under 35 U.S.C. 103(a) as being unpatentable over Friesen (CA 1,168,152) in view of de Burgh Bradley et al., (1,303,533) is maintained for reasons already of record.

Applicants assert that Bradley et al., cannot produce an immune globulin preparation for parenteral administration as it will be fatal. However, contrary to applicants arguments Bradley et al., teach antibody compositions comprising passive immunization with the claimed immune globulin for human injection comprised in a physiologically acceptable aqueous medium (page 13 lines 16-25).

Moreover, applicants pointing one particular immune globulin blend do not negate the teaching of the rest of the document. Bradley et al., teach plenty of methods of combining and administration which meet the claimed limitations.

The MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single

carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). Therefore applicant's argument is not persuasive especially when considering applicants, since Bradley et al., clearly teach an immune globulin for human parenteral administration.

Applicants argue that Bradley et al., does not teach advantageous reasons for combining polyoxyethylene sorbitan monooleate (TWENN 80). However it is the examiner's position that it would have been prima facie obvious at the time of applicants invention to modify either the method of increasing serum half-life by intravenously administering an immune globulin preparation comprising at least an immune globulin, sodium chloride and glycine as taught by Friesen in view of Bradley et al., who teach parenterally administering the same immune globulin preparations comprising several of the same reagents, yet further comprising a non-ionic surface active agent such as polyoxyethylene sorbitan monooleate. One would have a reasonable expectation of success in modifying the immune globulin preparation since the prior art already teaches preparations comprising non-ionic surface active agents as being advantageous in immune globulin preparation. Furthermore, no more than routine skill would have been required to incorporate well-known and commercially available reagents such as polyoxyethylene sorbitan monooleate within the immune preparation when the art already teaches their inclusion.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is

(703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

April 9, 2003